

K063399
FEB 23 2007

510(k) Summary
Aleutian Spacer System
K2M, Inc.

This safety and effectiveness summary for the Aleutian Spacer System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

K2M, Inc.
751 Miller Drive SE
Suite F1
Leesburg, VA 20175

Contact Person :

Richard W. Woods
K2M, Inc.
751 Miller Drive SE, Suite F1
Leesburg, VA 20175
Telephone: 703-777-3155

Date Prepared: November 6, 2006

2. Tradename: Aleutian Spacer System

Common Name: Vertebral Body Replacement Device

Classification Name: Spinal Intervertebral Body Fixation Orthosis (888.3060)

Product Code: MQP

3. Description of the device:

The Aleutian Spacer System consists of a hollow tube structure manufactured from Medical Grade PEEK (Polyetheretherketone). The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates.

Materials: The devices are manufactured from Medical Grade PEEK (Polyetheretherketone) OPTIMA® LT1 (Invibio™) per ISO 10993-1 USP Class VI and ASTM F2026. Tantalum beads /rods to be Grade UNS R05200, UNS R05400 according to ASTM F560.

Function: The system functions as a partial vertebral body replacement device to assist in fusion and to provide support and stabilization of the thoraco-lumbar segments of the spine.

4. Intended Use:

The Aleutian Spacer System is indicated for use in the thoracolumbar spine (T1 to L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aleutian Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The Aleutian Spacer System is intended to be used with supplemental internal fixation. The supplemental fixation systems that may be used with this implant are the Denali Spinal System, Denali Deformity and Mesa Spinal system.

5. Predicate or legally marketed devices which are substantially equivalent:

Documentation was provided which demonstrated that the subject Aleutian Spacer System components are substantially equivalent to the components previously cleared in the Aleutian Spacer System 510(k) K051454 (SE 07/27/2005).

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

There are no significant differences between the Aleutian Spacer System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

K2M, Inc.
% Mr. Richard W. Woods
751 Miller Drive, SE - Suite F1
Leesburg, Virginia 20175

FEB 23 2007

Re: K063399
Trade/Device Name: Aleutian Spacer System
Regulation Number: 21 CFR 888.3060
Regulation Name: spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: January 23, 2007
Received: January 26, 2007

Dear Mr. Woods:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Richard W. Woods

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurologic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K063399

Device Name : **Aleutian Spacer System**

Indications For Use : **K063399**

The Aleutian Spacer System is indicated for use in the thoracolumbar spine (T1 to L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aleutian Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The Aleutian Spacer System is intended to be used with supplemental internal fixation. The supplemental fixation system that may be used with this implant is the Denali Spinal System, Denali Deformity and Mesa Spinal system.

Prescription use X

OR

Over-the-counter use _____

(PER 21 CFR 801.109)

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruckner

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K063399